Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sinemet Plus 25 mg/100 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of Sinemet Plus 25 mg/100 mg contains carbidopa (equivalent to 25 mg of anhydrous carbidopa) and 100 mg levodopa.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets.

Products imported from Spain and Italy:
Yellow, oval tablets with '650' and a score line on one side and plain on the other. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses. If subdivided, the tablet should be consumed as a whole dose.

4 CLINICAL PARTICULARS

As per PA23198/004/003

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/004/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Quinoline yellow (E104)
Pregelatinised starch
Corn starch
Microcrystalline cellulose
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package to protect from light and moisture.

6.5 Nature and contents of container

PVC/AL blister packs of 100 tablets.

6.6 Special precautions for disposal

Not applicable.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/468/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 2021

10 DATE OF REVISION OF THE TEXT

February 2024